

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

Johnny W. Swoopes,

Plaintiff,

v.

JANSSEN RESEARCH &  
DEVELOPMENT, LLC f/k/a JOHNSON  
AND JOHNSON PHARMACEUTICAL  
RESEARCH AND DEVELOPMENT LLC;  
JOHNSON & JOHNSON COMPANY;  
JANSSEN ORTHO, LLC; JANSSEN  
PHARMACEUTICALS, INC. f/k/a  
JANSSEN PHARMACEUTICA INC., f/k/a  
ORTHO-MCNEIL-JANSSEN  
PHARMACEUTICALS, INC.; BAYER  
CORPORATION; BAYER HEALTHCARE  
LLC; and BAYER HEALTHCARE  
PHARMACEUTICALS INC.; and JOHN  
DOES 1-100,

Defendants.

**COMPLAINT AND DEMAND  
FOR JURY TRIAL**

**Civil Action No.:**

Plaintiff, Johnny W. Swoopes, by and through his undersigned counsel, upon information and belief, at all times hereinafter mentioned, allege as follows:

**JURISDICTION AND VENUE**

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. 1332, because the amount in controversy as to Plaintiff exceeds \$75,000.00, exclusive of costs, and because there is complete diversity of citizenship between Plaintiff and Defendants.

2. Venue is proper in this jurisdiction pursuant to 28 U.S.C. 1391, because a substantial part of the events or omission giving rise to the claim occurred in the District, and because Defendants' conduct substantial business in this District.
3. This Court has personal jurisdiction over the Defendants because they have done business in the State of New York, have committed a tort in whole or in part in the State of New York, have substantial and continuing contact with the State of New York, and derive substantial revenue from goods used and consumed within the State of New York. Defendants actively sell, market, and promote their pharmaceutical product Xarelto to physicians and consumers in the state in a regular and consistent basis.

### **PARTIES**

4. Plaintiff Johnny W. Swoopes ("Ingesting Plaintiff") at all times relevant hereto, was, and currently is, a resident and citizen of the State of Alabama. Upon information and belief, Ingesting Plaintiff suffered damages as a direct result of her ingestion of the pharmaceutical product Xarelto.
5. Defendant, JANSSEN RESEARCH & DEVELOPMENT, LLC (hereinafter "Janssen R & D"), f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC is a limited liability company organized, under the laws of New Jersey, with its principal place of business located at 920 U.S. Route 202, Raritan, New Jersey. Janssen R & D's sole principal or member is Centocor Research Development, Inc., (hereinafter "Centocor") a Pennsylvania corporation with its principal place of business and nerve center located at 200 Great Valley Parkway, Malvern, Pennsylvania. Centocor is a subsidiary or division of Johnson & Johnson,

and has locations involved in the research, design, marketing, sale, and distribution of Xarelto in Horsham, Malvern, Radner and Ambler, Pennsylvania.

6. Defendant JOHNSON & JOHNSON (hereinafter “J&J”), is a fictitious name adopted by Defendant JOHNSON & JOHNSON COMPANY, a New Jersey corporation which has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933. Defendant JOHNSON & JOHNSON was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Xarelto. Johnson & Johnson does business in New York and other states by, among other things, designing, developing, testing, manufacturing, labeling, packaging, distributing, marketing, selling and/or profiting from sales in New York and throughout the United States.
7. Defendant Janssen R & D is the holder of the approved New Drug Application (“NDA”) for Xarelto as well as the supplemental NDA. Janssen R & D, Johnson & Johnson and Centocor all transact substantial business within New York and within the Eastern District of New York, including the research, manufacture, sale, distribution and marketing of Xarelto, as set forth herein.
8. Defendant, JANSSEN ORTHO, LLC (“Ortho”) is a Delaware limited liability company with a principal place of business in Puerto Rico. Ortho is a subsidiary of Johnson & Johnson. At all times relevant hereto, Defendant Ortho manufactures, and continues to manufacture Xarelto. At all times relevant hereto, Defendant Ortho derived, and continues to derives, substantial revenue from goods and products developed, marketed, sold, distributed and disseminated and used in New York.

9. Defendant, JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. (“Janssen”), at all relevant times at the time suit was commenced, a Pennsylvania corporation with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. At all times relevant and material hereto, Janssen was, and still is, a pharmaceutical company involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Xarelto, in New York and specifically the Eastern District of New York and throughout the United States.
10. Defendant BAYER CORPORATION (“Bayer Corp”) is, and at all times relevant was and remains, an Indiana corporation with its nerve center, headquarters and principal place of business at 100 Bayer Road Pittsburgh, Pennsylvania. Bayer Corp. transacts substantial business within New York and specifically the Eastern District of New York including the research, manufacture, sale, distribution and marketing of Xarelto, as set forth herein.
11. Defendant, BAYER HEALTHCARE LLC (“Bayer HC”) is a Delaware limited liability company with its principal places of business located at 100 Bayer Road, Whippany NJ, 07981. Bayer HC’s sole member is Defendant Bayer Corporation which controls Bayer Pharmaceuticals which controls from its headquarters n Pittsburgh PA.
12. Bayer HC is a subsidiary of Bayer AG and jointly developed Xarelto with J&J and Janssen R & D. Bayer AG’s cooperation partner, J&J and Janssen R & D, submitted the new drug application for Xarelto to the FDA. Bayer HC transacts substantial business within New York and specifically the Eastern District of New York including

the research, manufacture, sale, distribution and marketing of Xarelto, as set forth herein.

13. Defendant, BAYER HEALTHCARE PHARMACEUTICALS INC. (“Bayer Pharma”) is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in 100 Bayer Road, Whippany NJ, 07981. Bayer Pharma is the U.S.-based pharmaceuticals operation of Bayer HC, a division of Bayer. Bayer Pharma is a subsidiary of Bayer and jointly developed, marketed and distributed Xarelto with J&J and Janssen R & D. At all times relevant and material hereto, Bayer Pharma was, and still is, a pharmaceutical company involved in the manufacturing, distribution, sale, and release for use to the general public of pharmaceuticals, including Xarelto in New York and specifically the Eastern District of New York and throughout the United States.
14. Bayer AG’s cooperating partner J&J and Janssen R & D submitted the new drug application to the FDA for Xarelto.
15. Defendants Janssen R & D, J&J, Ortho, Janssen, Bayer Corp, Bayer HC, and Bayer Pharma shall be referred to herein individually by name or jointly as “Defendants.”
16. At all times alleged herein, Defendants shall include any and all named or un-named parent companies, parent corporations, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and any organizational units of any kind, their predecessors, successors, successors in interest, assignees, and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

17. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessor in interest, aider and abettor, co-conspirator, and joint venturer of each of the remaining Defendants herein.
18. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessor in interest, aider and abettor, co-conspirator, and joint venturer of each of the remaining Defendants thereby operating and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.
19. At all times relevant and material hereto, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and or introducing into interstate commerce throughout the United States, and in New York, either directly or indirectly, through third-parties, subsidiaries and/or related entities, the anti-coagulant pharmaceutical Xarelto.

### **JURISDICTION AND VENUE**

20. Jurisdiction is proper over Defendants based on diversity of citizenship, 28 U.S.C. § 1332.
21. This Court has jurisdiction over Defendant Janssen R & D because Janssen R & D regularly conducts business, receives substantial revenues, markets and sells, and performs services in New York, specifically the Eastern District of New York. Janssen R & D regularly conducts business, sues and is sued in, receives substantial revenues, markets and sells, and performs services in New York, specifically the Eastern District of New York. At all times material and relevant hereto, Janssen R & D was, and still is, a pharmaceutical company involved in the development of the pharmaceutical drug

Xarelto in New York, specifically the Eastern District of New York and throughout the United States. A substantial part of Janssen R & D acts, omissions and events give rise to Plaintiff's injuries in this District.

22. This Court has jurisdiction over Defendant Janssen because Janssen was, and still is, a Pennsylvania corporation. Janssen regularly conducts business, sues and is sued in, receives substantial revenues, markets and sells, and performs services in New York, specifically the Eastern District of New York. At all times material and relevant hereto, Janssen was, and still is a pharmaceutical company involved in the manufacturing for pharmaceuticals, including Xarelto, for distribution and sale and use to the general public in New York, specifically the Eastern District of New York and throughout the United States. A substantial part Janssen's acts, omissions and events give rise to Plaintiff's injuries in this District.

23. This Court has jurisdiction over Defendant Bayer Corp because Bayer Corp is a Pennsylvania corporation and conducts substantial business in New York, specifically the Eastern District of New York. At all times material and relevant hereto, Bayer Corp was, and still is, a pharmaceutical company involved in pharmaceuticals, including Xarelto, for distribution and sale and use to the general public in New York, specifically the Eastern District of New York and throughout the United States. A substantial part Bayer Corp's acts, omissions and events give rise to Plaintiff's injuries in this District.

24. This Court has jurisdiction over Defendant Bayer HC because Bayer HC is a Pennsylvania corporation and conducts substantial business in New York, specifically the Eastern District of New York. At all times material and relevant hereto, Bayer HC was, and still is, a pharmaceutical company involved in the licensing of

pharmaceuticals, including Xarelto, for distribution and sale and use to the general public in New York, specifically the Eastern District of New York and throughout the United States. A substantial part Janssen's acts, omissions and events give rise to Plaintiff's injuries in this District.

25. This Court has jurisdiction over Defendant, Bayer Pharma because Bayer Pharma was, and still is, a pharmaceutical company involved in the manufacturing for pharmaceuticals, including Xarelto, for distribution and sale and use to the general public in New York, specifically the Eastern District of New York and throughout the United States. A substantial part Janssen's acts, omissions and events give rise to Plaintiff's injuries in this District.

26. This Court has jurisdiction over Defendant J&J, a New Jersey Corporation, because Defendant J&J conducts substantial business in New York, specifically the Eastern District of New York, committed torts in whole or in part in New York, specifically the Eastern District of New York, has systematic and continuous contacts with New York, specifically the Eastern District of New York, and/or has otherwise engaged in conduct subjecting to said Defendant to the reach of the applicable long-arm statutes.

27. This Court has personal jurisdiction over the Defendants pursuant to, and consistent with, New York's long-arm statute and both New York and Federal Constitutional requirements of Due Process in so far that Defendants, acting through agents or apparent agents, committed one or more of the following:

- a. Defendants transacted, and continues to transact, business in the New York, and conducted, and regularly conducts business, receives substantial revenues, and



sells and performs services in New York, specifically the Eastern District of New York;

b. Defendants have an interest in, uses, or possess real property in New York, specifically the Eastern District of New York;

c. Requiring Defendants to litigate this claim in New York, specifically the Eastern District of New York, does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution.

28. Venue is proper in this County because Defendants regularly conduct business in New York, specifically the Eastern District of New York.

29. This is an action for damages, exclusive of interest and costs, which exceeds the sum of seventy five thousand dollars (\$75,000.00).

#### **NATURE OF THE CASE – GENERAL ALLEGATIONS**

30. Defendants, directly or by and through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted, labeled, tested and sold Xarelto as an anti-coagulant primarily used to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat deep vein thrombosis (“DVT”), to treat pulmonary embolisms (“PE”), and/or to reduce the risk of recurrence of DVT and or PE.

31. Defendants applied for an initial NDA for Xarelto in July of 2008.

32. Xarelto was approved by the Food and Drug Administration (“FDA”) on July 1, 2011, to reduce risk of blood clots, DVT, and PE following knee and hip replacement surgery. On November 4, 2011 Xarelto was approved as an anticoagulant primarily used to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial

fibrillation On November 2, 2012 the FDA expanded to the of Xarelto to the treatment of patients with DVT and PE as well as long-term treatment to prevent recurrence of the same.

33. According to the Defendants' marketing and informational materials, referenced in the paragraphs below, and widely disseminated to the consuming public, "Xarelto® is the first and only once-a day prescription blood thinner for patients with AFib not caused by a heart valve problem, that is proven to reduce the risk of stroke – without routine blood monitoring."<sup>1</sup>

34. As the Defendants state on their website, "XARELTO® has been proven to lower the chance of having a stroke if you have atrial fibrillation (AFib), not caused by a heart valve problem. XARELTO® is an anticoagulant, or blood-thinning medicine that works by helping to keep blood clots from forming." The Defendants further claim that "it's been prescribed to more than seven million people around the world to help treat or reduce their risk of dangerous clots" and that it "begins working a few hours after you start taking it, and keeps working for as long as take it."<sup>2</sup>

35. Defendants further declare that "XARELTO® is proven to help treat and prevent DVT and PE blood clots" and that Xarelto "reduc[es] the risk of these dangerous clots [from] happening again."<sup>3</sup>

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<sup>1</sup><http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM357833.pdf>

<sup>2</sup> <http://www.xarelto-us.com/how-xarelto-works>

<sup>3</sup> <http://www.xarelto-us.com/dvt-pe/treatment-of-dvt-pe>

36. Defendants claim that patients with AFib, DVT, or PE taking Xarelto do not need regular blood monitoring and there are no known dietary restrictions. In addition, patients with AFib only need to take Xarelto once a day with an evening meal.<sup>4</sup>
37. Defendants claim that patients with AFib are five times more likely than a person without Afib to suffer from a stroke and that “disability is more likely to be severe” and “the outcome is almost twice as likely to be fatal” and “the chances of having another major stroke go up.”<sup>5</sup>
38. Rivaroxaban is an oxazolidinone derivative optimized for inhibiting both free Factor Xa and Factor Xa bound in the prothrombinase complex. It is a highly selective direct Factor Xa inhibitor with oral bioavailability and rapid onset of action. Inhibition of Factor Xa interrupts the intrinsic and extrinsic pathway of the blood coagulation cascade, inhibiting both thrombin formation and development of thrombi. Rivaroxaban does not inhibit thrombin (activated Factor II).
39. Defendants routinely marketed Xarelto as a “one size fits all” drug. In their fervent marketing of Xarelto, Defendants misinformed patients and their healthcare providers as to the necessity to routinely monitor any patient requiring a blood thinning agent. In essence, the Defendants have created a new drug, Xarelto, which is not better than warfarin from a safety perspective, and at best, perhaps slightly easier to use and administer. The idea of this apparently easier-to-use anticoagulant evidently appealed to physicians, who were subject to extreme marketing and promotion by the Defendants, but ignores patient safety.

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<sup>4</sup> <http://www.xarelto-us.com/dvt-pe/xarelto-difference#> and <http://www.xarelto-us.com/how-xarelto-is-different>

<sup>5</sup> <http://www.xarelto-us.com/knowning-your-stroke-risk>

40. The Defendants' marketing materials suggest that Xarelto represented a therapeutic simplification and therapeutic progress because it did not require patients to undergo periodic monitoring with blood tests and because there were no dietary restrictions.
41. Defendants' boxed warning did not address the increased risk for serious and fatal bleeding, despite the fact that the information listed on their website originating from the Rocket AF clinical trial sponsored by Defendants state that in comparison to warfarin, patients taking Xarelto have more gastrointestinal bleeds and need more transfusions. In spite of this reference regarding bleeds, the information is still wholly inadequate because this information was not conveyed in the boxed warning on the Xarelto label.<sup>6</sup>
42. According to Institute for Safe Medication Practices, QuarterWatch Report, issued on October 3, 2012, the primary reported adverse event related to Xarelto use "was not the well-understood risk of hemorrhage. Instead, the largest identifiable category was serious blood-clot-related injury—most frequently pulmonary embolism—the very events rivaroxaban is intended to prevent." This lack of efficacy for short term users of Xarelto post hip and knee replacement surgery resulted in about 44% of the reported adverse effects from taking Xarelto.
43. FDA clinical reviewers have stated that "rivaroxaban should not be approved unless the manufacturer conducts further studies to support the efficacy and safety of rivaroxaban" and the FDA website notes that "[a]dverse event reports of thrombocytopenia and venous thromboembolic events were identified" in relationship

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<sup>6</sup> <http://www.xareltohcp.com/reducing-stroke-risk/safety.html>

to Xarelto.<sup>7</sup> However, this information was not portrayed in the warning section on the warning label. The lack of efficacy of the medication for patients taking Xarelto after hip and knee surgery was not disclosed, resulting in patients ingesting Xarelto and physicians prescribing Xarelto without sufficient information to make an accurate decision.

44. Defendants fervently marketed Xarelto using print advertisements, online marketing on their website, and video advertisements with no regard to the accuracy and repercussions of their misleading advertising in favor of increasing sales.

45. In the January/February 2013 issue of *WebMD* magazine, Defendants placed a print advertisement that resulted in the Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) to send an untitled letter stating that their print advertisement was “false or misleading because it minimizes the risks associated with Xarelto® and makes a misleading claim.” Furthermore, the advertisement states “there are **no dosage adjustments**” in conflict with the product labeling approved by the FDA.<sup>8</sup>

46. As a result of Defendants’ intense marketing, “[a]bout 130,000 U.S. prescriptions were written for Xarelto® in the first three months of 2012” resulting in large profits as Xarelto costs approximately \$3,000 a year versus \$200 for generic warfarin.<sup>9</sup>

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<http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/ucm204091.htm>

<sup>8</sup><http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLettersToPharmaceuticalCompanies/UCM357833.pdf>, June 6, 2013 FDA Untitled Warning Letter

<sup>9</sup> Ransdell Pierson. “Pradaxa and Xarelto: Top Heart Doctors Concerned Over New Blood Thinners” *Huffpost Healthy Living*. 14<sup>th</sup> June 2012.

47. As a result of Defendant's extreme marketing tactics within the United Kingdom, Defendants also made 219 million Euros in sales from Xarelto, more than three times as much as during the same period last year.<sup>10</sup>

48. Due to the defective nature of Xarelto, persons who were prescribed and ingested Xarelto, for even a brief period of time, including Plaintiff, were at increased risk for developing life-threatening bleeds. Due to the flawed formulation of Xarelto, which according to Defendants does not require regular blood monitoring or frequent doctor follow-up, raises concerns about the risk of stroke, bleeding, and blood clots if not taken properly or absorbed properly, particularly in patients with poor renal function. In addition, "[p]rominent U.S. [cardiologists and health care professionals] stress that neither new drug [Xarelto] has a known antidote for a bleeding emergency, as warfarin does."<sup>11</sup>

49. Defendants' pharmaceutical Xarelto led to 968 suspected undesirable side-effects including 72 cases of death in Germany in just the first eight months of 2013.<sup>12</sup>

50. In addition, The Institute for Safe Medication Practices reported that:

A clinical trial with 14,000 patients had shown that rivaroxaban was no worse than warfarin. [40] But reviewers noted that warfarin had not been optimally used. If rivaroxaban were really inferior to optimally used warfarin—but this was not proven, only suspected—its use could lead to increased death and injury. [41] Reviewers also questioned the convenient once-a-day dosing scheme, saying blood level studies had shown peaks and troughs that could be eliminated by

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<sup>10</sup> Frank Siebelt, Hans Seidenstuecker, and Christoph Steitz. "Reports of side-effects from Bayer's Xarelto grow: Spiegel" <http://www.reuters.com/article/2013/09/08/us-bayer-xarelto-idUSBRE9870AH20130908>

<sup>11</sup> Ransdell Pierson. "Pradaxa and Xarelto: Top Heart Doctors Concerned Over New Blood Thinners" *Huffpost Healthy Living*. 14<sup>th</sup> June 2012.

<sup>12</sup> Frank Siebelt, Hans Seidenstuecker, and Christoph Steitz. "Reports of side-effects from Bayer's Xarelto grow: Spiegel" <http://www.reuters.com/article/2013/09/08/us-bayer-xarelto-idUSBRE9870AH20130908>

twice-a-day dosing. ... As with other anticoagulants, the rate of clinically relevant bleeding in clinical studies was high—15% per year of treatment.<sup>13</sup>

In other words, the insufficient testing conducted and the deadly consequences of Xarelto did not go unnoticed.

51. Even more significantly, in the first quarter of 2012, The Institute for Safe Medication Practices “identified 356 reports of serious, disabling, or fatal injury in which rivaroxaban was the primary suspect drug. The report more than doubled from the previous quarter total of 128 cases.”<sup>14</sup> However, when the findings were discussed with Defendants, “the company told us that it had reviewed the same data and saw no signal of a safety issue that needed to be addressed.”<sup>15</sup> Defendants placed more value into ensuring that their profits would continue instead of working on minimizing the serious, disabling, or fatal injuries that were occurring due to the drug they were marketing and promoting.

52. Defendants concealed their knowledge that Xarelto can cause life threatening, irreversible bleeds from Plaintiff, other consumers, the general public, and the medical community. Indeed, the Defendants did not properly warn of the irreversible nature of Xarelto in the “Warnings and Precautions” section of the products warning label. The only warnings provided by Defendants were as follows:

- WARNINGS AND PRECAUTIONS-----**
- Risk of bleeding: XARELTO can cause serious and fatal bleeding. Promptly evaluate signs and symptoms of blood loss. (5.2)
  - Pregnancy related hemorrhage: Use XARELTO with caution in pregnant women due to the potential for obstetric hemorrhage and/or emergent delivery. Promptly evaluate signs and symptoms of blood loss. (5.7)
  - Prosthetic heart valves: XARELTO use not recommended (5.8)

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<sup>13</sup> Institute for Safe Medication Practices, QuarterWatch Report, October 3, 2012

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

Specifically, Defendants did not adequately inform consumers and the prescribing medical community about the risks of uncontrollable bleeds associated with Xarelto usage, nor did Defendants warn or otherwise advise on how to intervene and stabilize a patient should a bleed occur.

53. As seen in the “Full Prescribing Information” provided by Defendants, Defendants reveal that they did not test for all the possible reversal agents for this dangerous drug since “[a] specific antidote for rivaroxaban is not available” and “[u]se of procoagulant reversal agents such as prothrombin complex concentrate (PCC), activated prothrombin complex concentrate (APCC), or recombinant factorVIIa (rFVIIA) may be considered but has not been evaluated in clinical trials.” However, this is buried in small print.

54. Importantly, Xarelto still does not have a “black box” warning informing patients or prescribing doctors know that Xarelto can cause irreversible bleeds. In fact, the August 2013 Highlights of Prescribing Information only has a “black box” warning stating the following:

**WARNING: (A) PREMATURE DISCONTINUATION OF XARELTO INCREASES THE RISK OF THROMBOTIC EVENTS, and (B) SPINAL/EPIDURAL HEMATOMA**  
*See full prescribing information for complete boxed warning*

**PREMATURE DISCONTINUATION OF XARELTO INCREASES THE RISK OF THROMBOTIC EVENTS**  
Premature discontinuation of any anticoagulant, including XARELTO, increases the risk of thrombotic events. To reduce this risk, consider coverage with another anticoagulant if XARELTO is discontinued for a reason other than pathological bleeding or completion of a course of therapy (2.2, 2.6, 5.1, 14.1).

**SPINAL/EPIDURAL HEMATOMA**  
Epidural or spinal hematomas have occurred in patients treated with XARELTO who are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis (5.2, 5.3, 6.2).  
Monitor patients frequently for signs and symptoms of neurological impairment and if observed, treat urgently. Consider the benefits and risks before neuraxial intervention in patients who are or who need to be anticoagulated (5.3).



55. Even in the “Warnings and Precautions” section of the August 2013 Highlights of Prescribing Information, the irreversible nature of the medication Xarelto was not revealed to patients or their prescribing doctors. Defendants merely indicated that there was a risk for bleeding and side-stepped the important issue of reversing the effects of Xarelto should a bleed occur as seen below:

**-----WARNINGS AND PRECAUTIONS-----**

- Risk of bleeding: XARELTO can cause serious and fatal bleeding. Promptly evaluate signs and symptoms of blood loss. (5.2)
- Pregnancy related hemorrhage: Use XARELTO with caution in pregnant women due to the potential for obstetric hemorrhage and/or emergent delivery. Promptly evaluate signs and symptoms of blood loss. (5.7)
- Prosthetic heart valves: XARELTO use not recommended (5.8)

56. Aside from the warning labels, Defendants did not issue a Dear Doctor letter that sufficiently outlined the dangers of administering Xarelto to a patient. In the September 2013 letter to healthcare professionals, Defendants do not mention the lack of an antidote in Xarelto should serious and fatal bleeding occur while a patient was taking Xarelto.

57. The current warning is simply inadequate. The Defendants have failed and continue to fail in their duties to warn and protect the consuming public, including Plaintiff.

58. Even if the warnings were sufficient, which Plaintiff strongly denies, Xarelto still lacks any benefit sufficient to tolerate the extreme risk posed by the ingestion of this drug. Xarelto is quite simply dangerous and defective as formulated. The Defendants should withdraw Xarelto from the market.

59. Defendants willfully, wantonly and with malice withheld the knowledge of increased risk of irreversible bleeds in users of Xarelto to prevent any chances of their product's registrations being delayed or rejected by FDA.

60. As the manufacturers and distributors of Xarelto, Defendants knew or should have known that Xarelto use was associated with irreversible bleeds.
61. With the knowledge of the true relationship between use of Xarelto and irreversible bleeds, rather than taking steps to pull the drug off the market, provide strong warnings, or create an antidote, Defendants promoted and continue to promote Xarelto as a safe and effective treatment for AFib.
62. Defendants' "Xarelto®...is estimated to be the 19th-best-selling drug in the world by 2018, according to the report. Worldwide sales of Xarelto® are expected to jump from \$596 million in 2012 to \$3.7 billion in 2018."<sup>16</sup>
63. While Defendants enjoy great financial success from their expected blockbuster drug, Xarelto, they continue to place American citizens at risk of severe bleeds and death.
64. Consumers, including Plaintiff, who have used Xarelto to reduce the risk of stroke due to Afib or to reduce the risk of blood clots, DVT and PE following knee or hip replacement surgery, have several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits, associated with Xarelto therapy.
65. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with Xarelto use.
66. As a result of Defendants' actions, Plaintiff and Plaintiff's physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff would be exposed to the risks identified in this Complaint. The increased risks

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<sup>16</sup> <http://www.drugwatch.com/2013/07/23/blood-thinner-growth-more-risk/>

and subsequent medical damages associated with Plaintiff's Xarelto use were the direct and proximate result of Defendants' conduct.

### **FACTUAL ALLEGATIONS**

67. Upon information and belief, in or around June 2013, Plaintiff was first prescribed Xarelto, also known as rivaroxaban, in the State of Alabama, upon direction of Plaintiff's physician to prevent blood clots. Subsequently, as a direct result of Plaintiff's ingestion of Xarelto, upon information and belief, Plaintiff was admitted, treated and discharged from Decatur Morgan Hospital in Decatur, Alabama, on or about December 9, 2013. Plaintiff suffered severe internal bleeding including rectal and gastrointestinal bleeding, requiring hospitalization for approximately five days, during which time he underwent multiple blood transfusions and numerous diagnostic tests.
68. Upon information and belief, as a direct result of being prescribed Xarelto for this period of time, Plaintiff has suffered significant injuries, such as those described above.
69. Upon information and belief, as a proximate result of Defendants' acts and omissions, Plaintiff suffered the injuries described hereinabove due to Plaintiff's ingestion of Xarelto. Plaintiff accordingly seeks damages associated with these injuries.
70. Plaintiff would not have used Xarelto had Defendants properly disclosed the risks associated with its use.
71. The injuries and damages sustained by Plaintiff were caused by Defendants' Xarelto.

### **COUNT I:**

**STRICT PRODUCTS LIABILITY**

72. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:
73. At all times relevant and material hereto, Defendants were engaged in the business of designing, manufacturing, testing, marketing, and placing into the stream of commerce pharmaceuticals, including the Xarelto at issue in this lawsuit, for the sale to, and use by, members of the public. The Xarelto manufactured by Defendants reached Plaintiff without substantial change and was ingested as directed. The Xarelto manufactured by Defendants was defective and unreasonably dangerous when it entered into the stream of commerce and when used by Plaintiff.
74. Defendants, as manufacturers and distributors of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known that warnings and other clinically relevant information and data which they distributed regarding the risks of irreversible bleeds and other injuries and death associated with the use of Xarelto were inadequate.
75. Plaintiff did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to Plaintiff or to Plaintiff's treating physicians.
76. Defendants had a continuing duty to provide consumers, including Plaintiff and Plaintiff's physicians, with warnings and other clinically relevant information and data regarding the risks and dangers associated with Xarelto, as it became or could have become available to Defendants.

77. Defendants marketed, promoted, distributed and sold an unreasonably dangerous and defective prescription drug, Xarelto, to health care providers empowered to prescribe and dispense Xarelto to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data. Through both omission and affirmative misstatements, Defendants misled the medical community about the risk and benefit balance of Xarelto, which resulted in injury to Plaintiff.

78. Despite the fact that Defendants knew or should have known that Xarelto caused unreasonable and dangerous side effects, they continued to promote and market Xarelto without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data.

79. Defendants knew or should have known that consumers, including Plaintiff, would foreseeably and needlessly suffer injury or death as a result of Defendants' failures.

80. Defendants failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Plaintiff and to Plaintiff's physicians, in the following ways:

- a. Defendants failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Plaintiff and Plaintiff's physicians to the dangerous risks of Xarelto including, among other things, irreversible bleeds;
- b. Defendants failed to provide adequate post-marketing warnings and instructions after the Defendants knew or should have known of the significant risks of, among other things, irreversible bleeds;

c. Defendants continued to aggressively promote and sell Xarelto, even after they knew or should have known of the unreasonable risks of irreversible bleeds from this drug.

81. Defendants had an obligation to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Xarelto, and/or that there existed safer and more or equally effective alternative drug products.

82. By failing to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Xarelto, and/or that there existed safer and more or equally effective alternative drug products, Defendants breached their duty of reasonable care and safety.

83. Defendants' actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of Plaintiff and the general public.

84. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Plaintiff was exposed to Xarelto and suffered the injuries and damages set forth hereinabove.

85. As to **Count I- Strict Products Liability**, Plaintiff reserve its rights to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

#### **COUNT II: NEGLIGENCE**

86. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

87. Defendants owed a duty to the general public, and specifically to Plaintiff, to exercise reasonable care in the design, study, development, manufacture, promotion, sale, marketing and distribution of their prescription medications, including the Xarelto at issue in this lawsuit. Defendants failed to exercise reasonable care in the design of Xarelto because as designed, Xarelto was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use. Defendants also failed to exercise reasonable care in the marketing of Xarelto because they failed to warn, that as designed, Xarelto was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use.

88. Defendants breached their duty and were negligent in, but not limited to, the following actions, misrepresentations, and omissions toward Plaintiff:

- a. Failing to use due care in developing, testing, designing, and manufacturing Xarelto so as to avoid the aforementioned risks to individuals when Xarelto was being used for treatment;
- b. Failing to accompany their product with proper or adequate warnings, or labeling regarding adverse side effects and health risks associated with the use of Xarelto and the comparative severity and duration of such adverse effects;
- c. In disseminating information to Plaintiff and Plaintiff's physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff;
- d. Failing to accompany their products with proper or adequate rate of incidence or prevalence of irreversible bleeds;

- e. Failing to provide warnings or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks;
- f. Failing to conduct adequate pre-clinical and clinical testing and post- marketing surveillance to determine the safety of Xarelto;
- g. Failing to warn Plaintiff, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative medications available to Plaintiff and other consumers;
- h. Failing to provide adequate training or information to medical care providers for appropriate use and handling of Xarelto and patients taking Xarelto;
- i. Failing to adequately test and/or warn about the use of Xarelto, including, without limitations, the possible adverse side effects and health risks caused by the use of Xarelto;
- j. Failing to design and/or manufacture a product that could be used safely due to the lack of a known reversal agent or antidote;
- k. In designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable use, which Defendant knew or should have known could cause injury to Plaintiff;
- l. Failing to remove Xarelto from the market when Defendants knew or should have known of the likelihood of serious side effects and injury to its users;
- m. Failing to adequately warn users, consumers and physicians about the severity, scope and likelihood of bleeds and related dangerous conditions to individuals taking Xarelto; and



n. Representing to physicians, including but not limited to Plaintiff's prescribing physicians, that this drug was safe and effective for use.

89. The Xarelto that injured Plaintiff was in substantially the same condition when Plaintiff ingested it as it was in when it left the control of Defendants. Xarelto's ability to cause serious personal injuries and damages, such as those suffered by Plaintiff, was not due to any voluntary action or contributory negligence of Plaintiff. Plaintiff consumed the Xarelto as directed and without change in its form or substance.

90. Defendants' failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Xarelto was a proximate cause of Plaintiff's injuries and damages.

91. Plaintiff seeks all damages to which Plaintiff may be justly entitled.

92. Plaintiff's injuries and damages are severe and permanent, and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from the Defendants.

93. As to **Count II-Negligence**, Plaintiff reserves the right to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

**COUNT III: NEGLIGENCE- FAILURE TO WARN**

94. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

95. Xarelto was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert patients and prescribing physicians of the dangerous risks and reactions associated with Xarelto, including but not limited to the prevalence of irreversible bleeding, and other serious injuries and side

effects despite Defendants' knowledge of the increased risk of these injuries over other anticoagulation therapies available.

96. Xarelto was defective due to inadequate post-marketing warnings and instruction because Defendants knew or should have known of the risk and danger of serious bodily harm and or death from the use of Xarelto but failed to provide an adequate warning to patients and prescribing physicians of the product, knowing the product could cause serious injury and or death.

97. Plaintiff was prescribed and used Xarelto for its intended purpose.

98. Plaintiff could not have known about the dangers and hazards presented by Xarelto.

99. The warnings that were given by Defendants were not accurate, clear, compete, and/or were ambiguous.

100. The warnings, or lack thereof, that were given by Defendants failed to properly warn prescribing physicians of the risk of irreversible bleeding and other serious injuries and side effects, and failed to instruct prescribing physicians to test and monitor for the presence of the injuries for which Plaintiff and others had been placed at risk.

101. The warnings that were given by the Defendants failed to properly warn Plaintiff and prescribing physicians of the prevalence of irreversible bleeds.

102. Plaintiff, individually and through her prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendants. Defendants had a continuing duty to warn Plaintiff and prescribing physicians of the dangers associated with Xarelto. Had Plaintiff received adequate warnings regarding the risks of Xarelto, she would not have used Xarelto.

103. As a direct and proximate result of Xarelto's defective and inappropriate warnings, Plaintiff has suffered severe physical injuries and damages as described above.
104. As a direct and proximate result of the wrongful acts of Defendants, Plaintiff suffered severe and irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; incurred and will continue to incur expenses for medical treatment of Plaintiff's injuries; suffered and will continue to suffer the loss of enjoyment of life and has been otherwise damaged to be further shown by the evidence.
105. For the above reasons, Defendants are strictly liable under New York and/or Alabama product liability law without regard to proof of negligence or gross negligence.
106. As to **Count III-Negligence- Failure to Warn**, Plaintiff reserves the right to amend this cause of action or seek a court order to apply any applicable law of the Plaintiff's home state.

**COUNT IV: NEGLIGENCE – UNREASONABLE MARKETING OF A DANGEROUS  
DRUG AND UNREASONABLE FAILURE TO REMOVE THE DRUG FROM THE  
MARKET**

107. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:
108. Defendants owed a duty to the general public, and specifically to Plaintiff, to not introduce a drug into the market, or continue a previous tender of a drug, including the Xarelto at issue in this lawsuit, that was unreasonably dangerous for any person to use it and was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use.
109. Defendants breached their duty of care and were negligent by, but not limited to, the following actions, misrepresentations, and omissions toward Plaintiff:

- a. Failing to exercise reasonable and ordinary care in that the drug Xarelto was so unreasonably dangerous and defective in design that it never should have been on the market or taken by anyone;
- b. Failing to exercise reasonable and ordinary care in the design, research, development, manufacture, sale, testing and or distribution of the drug Xarelto.
- c. Tendering into the market a drug which Defendants knew or should have known was so dangerous that it shouldn't have been taken by anyone.
- d. Violating its duty of care in design by tendering into the market a drug which it knew or should have known should not have been taken by anyone.
- e. Violating its duty of care in design in marketing by tendering into the market a drug which it knew or should have known should not have been taken by anyone.
- f. Violating its duty of care in design by placing an unsuitable product into the market for public consumption.

110. The Xarelto that injured Plaintiff was in substantially the same condition when Plaintiff ingested it as it was in when it left the control of Defendants. Xarelto's ability to cause serious personal injuries and damages such as those suffered by Plaintiff was not due to any voluntary action or contributory negligence of Plaintiff. Plaintiff consumed the Xarelto as directed and without change in its form or substance.

111. Defendants' violation of its duty of care resulted in an untenably dangerous product being placed into the marketplace which was a proximate cause of Plaintiff's injuries and damages.

112. Plaintiff seeks all damages to which Plaintiff may be justly entitled.

113. Plaintiff's injuries and damages are severe and permanent, and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from the Defendants.

114. As to **Count IV- Negligence, Unreasonable Marketing of a Dangerous Drug and Unreasonable Failure to Remove the Drug from the Market**, Plaintiff reserves the right to amend this cause of action or seek a court order to apply any applicable law of the Plaintiff's home state.

**COUNT V: BREACH OF WARRANTY - BREACH OF EXPRESS WARRANTY**

115. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

116. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce Xarelto, in the course of same, directly advertised or marketed the product to the FDA, healthcare professionals and consumers, including Plaintiff, or persons responsible for consumers.

117. Xarelto materially failed to conform to those representations made by Defendants in package inserts, and otherwise, concerning the properties and effects of Xarelto, respectively manufactured and/or distributed and sold by Defendants, and which Plaintiff purchased and ingested in direct or indirect reliance upon these express representations. Such failures by Defendants constituted a material breach of express warranties made, directly or indirectly, to Plaintiff concerning Xarelto sold to Plaintiff.

118. As a direct, foreseeable, and proximate result of Defendants' breaches of express warranties, Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when Plaintiff's physician, in reasonable reliance upon such

express warranties, prescribed for Plaintiff the use of Xarelto. Plaintiff purchased and ingested Xarelto as prescribed and instructed by Plaintiff's physician, leading to Plaintiff's injuries.

119. Plaintiff's injuries and damages are severe and permanent, and will continue into the future. As a result, the Plaintiff seeks actual and punitive damages from the Defendants.

120. As to **Count V- Breach of Warranty, Breach of Express Warranty**, Plaintiff reserves the right to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

**COUNT VI: BREACH OF WARRANTY – BREACH OF IMPLIED WARRANTY**

121. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

122. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce Xarelto, in the course of same, directly advertised or marketed the product to the FDA, health care professionals and consumers, including Plaintiff, or persons responsible for consumer.

123. Defendants impliedly warranted their Xarelto product, which they manufactured and/or distributed and sold, and which Plaintiff purchased and ingested, to be of merchantable quality and fit for the common, ordinary, and intended uses for which the product was sold.

124. Defendants breached their implied warranties of the Xarelto product sold to Plaintiff because this product was not fit for its common, ordinary, and intended use.

125. As a direct, foreseeable and proximate result of Defendants' breaches of implied warranties, Plaintiff suffered grievous bodily injury and consequential economic and other losses, as described above, when Plaintiff ingested Xarelto, in reasonable reliance upon the implied warranties, leading to Plaintiff's injuries.
126. Plaintiff's injuries and damages are severe and permanent, and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from Defendants.
127. As to **Count VI- Breach of Warranty, Breach of Implied Warranty**, Plaintiff reserves the right to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

**COUNT VII: FRAUD**

128. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:
129. Defendants, having undertaken the manufacturing, marketing, dispensing, distribution and promotion of Xarelto described herein, owed a duty to provide accurate and complete information regarding these products.
130. Defendants knew or should have known, that Xarelto was unreasonably dangerous and defective, and caused serious, at times fatal, irreversible bleeds.
131. Despite their knowledge, Defendants omitted material facts in the disclosures they made to the public, the medical community and to consumers, including Plaintiff and Plaintiff's prescribing physicians, concerning the use and safety of Xarelto.
132. Defendants made untrue, deceptive, and/or misleading representations of material facts, and omitted and/or concealed material facts from the public, including Plaintiff and Plaintiff's prescribing physicians, concerning the use and safety of Xarelto.

133. Defendants' practices relating to their promotion of Xarelto created and/or reinforced a false impression as to its safety.
134. Defendants' practice of promoting Xarelto placed and continues to place all consumers of Xarelto at risk for serious injury resulting from its potentially lethal side effects.
135. Defendants' statements and omissions were made with the intent that Plaintiff, and Plaintiff's prescribing physicians would rely on them.
136. Plaintiff purchased and used Xarelto for personal, family or household purposes and suffered ascertainable losses of money as a result of the Defendants' use or employment of the methods, acts, or practices.
137. As a direct and proximate result of the Defendants' acts of fraud, Plaintiff suffered irreparable injuries.
138. Plaintiff endured substantial pain and suffering. As a result, Plaintiff has incurred significant expenses for medical care and will continue to be economically and emotionally harmed in the future.
139. Plaintiff's injuries and damages are severe and permanent, and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from the Defendants.
140. As to **Count VII-Fraud**, Plaintiff reserves the right to amend this cause of action or seek a court order to apply any applicable law of the Plaintiff's home state.

**COUNT VIII: VIOLATION OF CONSUMER PROTECTION LAWS**

141. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:



142. Plaintiff purchased and used Xarelto for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.
143. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:
- a. Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;
  - b. Advertising goods or services with the intent not to sell them as advertised; and
  - c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.
144. Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of Xarelto.
145. Defendants uniformly communicated the purported benefits of Xarelto while failing to disclose the serious and dangerous side-effects related to the use of Xarelto and of the true state of Xarelto regulatory status, its safety, its efficacy, and its usefulness. Defendants made these representations to physicians, the medical community at large, and to patients and consumers such as Plaintiff in the marketing and advertising campaign described herein.
146. Defendants' conduct in connection with Xarelto was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely and or deceptively misrepresented and omitted numerous material

facts regarding, among other things, the utility, benefits, costs, safety, efficacy and advantages of Xarelto.

147. As a result of these violations of consumer protection laws, Plaintiff has incurred and will incur; serious physical injury, pain, suffering, loss of income, loss of opportunity, loss of family and social relationships, and medical, hospital and surgical expenses and other expense related to the diagnosis and treatment thereof, for which Defendants are liable.

148. As to **Count XIII-Violation of Consumer Protection Law**, Plaintiff reserves the right to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

**COUNT IX:**  
**DAMAGES- COMPENSATORY AND PUNITIVE**

134. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

135. Plaintiff is entitled to punitive damages because Defendants' actions were reckless and without regard for the public's safety. Defendants mislead both the medical community and the public at large, including Plaintiff and Plaintiff's physicians, by making false representation about and concealing pertinent information regarding Xarelto. Defendants downplayed, understated and disregarded its knowledge of the serious and permanent side effects associated with the use of Xarelto despite information demonstration the product was unreasonably dangerous.

136. As a proximate result of Defendants' acts and omissions, Plaintiff suffered internal and gastrointestinal bleeding, all resulting from Plaintiff's ingestion of Xarelto.

137. As a result of Plaintiff's injuries, Plaintiff has endured substantial pain and suffering; has incurred significant expenses for medical care, and will remain economically challenged and emotionally harmed.

138. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured.

139. Defendants' actions were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiff and the public.

140. Plaintiff's injuries and damages are severe, permanent and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from Defendants.

141. Defendants' conduct was committed with knowing, conscious and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

142. As to **Count IX- Damages, Compensatory and Punitive**, Plaintiff reserves the right to amend this cause of action or seek a court order to apply any applicable law of Plaintiff's home state.

### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff demands judgment against the Defendants on each of the above referenced claims and pray for relief against Defendants as follows:

1. For economic damages in the form of medical expenses judgment for damages sufficient to compensate for damages, including but not limited to past, present, and future economic expenditures in connection with the injuries sustained by Plaintiff as a result of ingesting Defendants' Xarelto drug product;

2. For compensatory damages in excess of the jurisdictional amount, including but not limited to, lost wages, pain, suffering and mental anguish and any and all damages allowed under applicable law;
3. For punitive damages, in an amount to be awarded as provided by law;
4. For reasonable costs, including attorney's fees as permitted by law; and
5. For all other just and proper relief.

Dated: December 10, 2014

**NAPOLI BERN RIPKA SHKOLNIK &  
ASSOCIATES, LLP**

BY:

/s/ Shayna E. Sacks  
Shayna E. Sacks  
Napoli Bern Ripka Shkolnik, LLP  
350 Fifth Ave, Suite 7413  
New York, NY 10118  
(212) 267-3700

**JURY DEMAND**

Plaintiff hereby demands a trial by jury on all issues.

Dated: December 10, 2014

**NAPOLI BERN RIPKA SHKOLNIK &  
ASSOCIATES, LLP**

BY:

/s/ Shayna E. Sacks  
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